



PATENT
Attorney Docket No. HAR-001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Michael Harris } *Art Unit:* 3771
 }
Serial No. 10/660,429 } *Examiner:* Teena Kay Mitchell
 }
Filing Date: September 12, 2003 }

Title: Methods for the treatment of HIV and other viruses

AFFIDAVIT UNDER 37 CFR § 1.132

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Michael Harris, declare and state as follows.

1. I am President of M.F. Harris Research and am sole inventor of the above-identified patent application.

2. I have twenty-six years of experience in research and patient care.

3. A listing of my education and training are provided in my Curriculum Vitae supplied with the attached Appendix as Exhibit 1. My graduate/advanced training was obtained at Georgetown University School of Medicine, Saba University School of Medicine, the University of Virginia School of Medicine, the Medical College of Virginia and Duke University. I have done research on the topic of the invention at the Medical College of Virginia, Duke University, and with the company M.F. Harris Research.

4. I am familiar with the prosecution of the above-identified Application.

5. I have read the Office Action dated June 26, 2007.

6. I understand the Examiner has rejected claims 1-18 as obvious over Harris (Pilot Study to Assess the Efficacy of Intermittent Hyperbaric Nitrogen Treatment of Acquired Immunodeficiency Syndrome) in view of Risley et al. (U.S. Patent No. 7,198,045).

7. I understand that the Harris reference, which has no publication information, was submitted anonymously to the Patent Office as a printed publication, with an anonymous statement that it was "circulated in 1998".

8. I declare that the cited Harris reference was, *inter alia*, never a printed publication and was not public before the filing of the present application, and that the assertion by the anonymous person is either a blatant falsehood or a statement based on a lack of knowledge of what is confidential. This document was never presented to anyone except in a confidential manner. I present information and discussion below declaring that the cited Harris reference is not a printed publication and was never available publicly before the filing of the instant application.

9. I declare that the cited Harris reference was a confidential research proposal submitted to the Medical College of Virginia as part of the approval process needed for approval by the Institutional Review Board ("IRB") at the Medical College of Virginia, where I was a student at the time. As indicated on the cover page of the cited Harris reference, my name, status as a "Medical Student Principal Investigator", the institution where I was a student at the time (Medical College of Virginia), and the date (March 16, 1998) of the confidential proposal are provided. The proposal process is a confidential one, as described below.

10. As evidenced by the content of the cited Harris reference, the reference merely presents a hypothesis and a proposal for a study. In fact, no data are provided in the cited Harris reference, because it was merely a proposal.

11. Further indication that the cited Harris reference was a confidential proposal submitted to the Medical College of Virginia is the fact that at page 4, under the section "Clinical and Experimental Protocol", the section begins with the phrase "This protocol proposes . . ." and goes on to outline the proposed objectives in the proposal, how patients will be selected and managed, how the patients will be evaluated, and how the results will be subjected to statistical analyses.

12. Even more explicit proof that the Harris document was submitted as a proposal is the stipulation on page 8 under the section entitled "Human Subjects" that the protocol will be administered to conform with the **IRB** and FDA standards and that patient confidentiality will be maintained. Further provided at pages 10 to 13 of the cited Harris reference is a copy of the Informed consent document that was to be signed by patients who agreed to participate in the study, which further describes the confidentiality that would be maintained.

13. Such human research proposal submissions are kept in confidence and are not available to the public, thus the cited Harris reference cannot be used as prior art. In fact, proposals under review at Institutional Review Boards of universities are not even available under the Freedom of Information Act. Proof of this confidentiality is provided herewith by way of a copy of an opinion issued by the Attorney General of Virginia, where Medical College of Virginia is located, issued as Opinion # 01-101 (provided in the Appendix as Exhibit 2). The link to the State of Virginia website where the Opinion can also be found is at <http://www.oag.state.va.us/OPINIONS/2001opns/oct01ndx.htm>. The opinion was released in October 2001. It is the first opinion listed on the web page and is listed as Opinion # 01-101 in the left column. The opinion can be seen by clicking on the "01-101" on the web page. The center column of that web page indicates that the requestor of the opinion was The Honorable Thomas C. Wright Jr., who was a member of the Virginia House of Delegates. The right column of that web page lists the summary of the opinion in response to Delegate's question about confidentiality relative to the Freedom of Information Act and states:

Attorney Docket No. HAR-001
Patent Application Serial No. 10/660,429
1.132 Declaration for Response to 6/27/07 Office Action

"Institutional Review Board is not 'public body' subject to the Act's disclosure requirements. Records generated by such board are not 'public records' prepared, owned or possessed by public body; are not required to be open for public inspection. Act's open meeting requirement does not apply to meetings of Institutional Review Boards and human research review committees." (emphasis added).

A copy of that web page is provided as well herewith and is listed as Exhibit 3 in the Appendix. The statement cited above is also the first statement in the Opinion (Exhibit 2) issued the Attorney General of Virginia. This opinion also conforms with U.S. law for maintaining proposal, protocol, and patient information confidential.

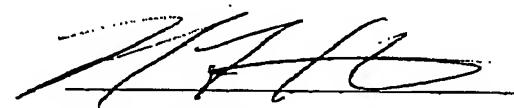
14. For these reasons, I assert that my research proposal, the document cited as Harris in the 103 rejection, was not a printed publication or a public document.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Respectfully submitted,

Date:

9/26/07



Michael Harris

Appendix to 1.132 Declaration by Michael F. Harris

List of Exhibits

Exhibit 1- Curriculum vitae of Michael Harris

Exhibit 2- Document from the Attorney General's Office of the State of Virginia stating that human research proposals submitted to the Institutional Review Boards of Medical Schools are confidential documents and furthermore are not even accessible by the Freedom of Information Act

Exhibit 3- A copy of the State of Virginia web page where the link to the Opinion of Exhibit 2 can be found (<http://www.oag.state.va.us/OPINIONS/2001opns/oct01ndx.htm>)

Cirriculum Vitae
Michael F. Harris

9/27/2007

MICHAEL FRANKLIN HARRIS

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Luray, Virginia 22835
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PROFESSIONAL EXPERIENCE

June, 1999 to Present

M. F. HARRIS RESEARCH/ NITRAIDS

Durham, North Carolina

Founder. Acting CEO Patented method of treatment for viral infections and other applications registry # 60/137,734, Phase I trials completed. Corporation set up to perform research contracted at Duke University. SBIR grant and scientific paper writing. Coordinating all aspects of science/technology and business proposals/negotiations. Principal owner.

April, 1994 to Present

M.F. HARRIS RESEARCH

Richmond, Virginia

President set up corporation to handle management of research funding and studies. Design and promote research studies. Coordinate specialist and principal investigators to obtain Institutional Review Board approval for proposed clinical studies. File annual report and tax returns.

July, 1993 to Present

SCHOOL of PHARMACY, MEDICAL COLLEGE of VIRGINIA, PHARMACODYNAMIC RESEARCH GROUP/VETERANS ADMINISTRATION, MCGUIRE RESEARCH INSTITUTE

Richmond, Virginia

Data Administrator. Coordinated clinical research data with project management to produce phase I case report forms for leading drug companies. Duties included: development of systems for collection of raw data without errors, lab work tracking and filing; transfer from manual to electronic transcription of raw data to case report forms, identifying project load and assigning personnel accordingly, frequent interactions with C.S.U. staff, project management and client representatives to retrieve data for accurate completion of case report forms and data clarification forms in a timely manner; training personnel; continuous system review; development of Standard Operating Procedures.

9/27/2007

October, 1992 to April, 1993 **JEFFERSON DIALYSIS**

Charlottesville, Virginia

Dialysis Therapist - Day, Holiday Shifts - Patient care included: cannulation of A/V fistulas and Gore-Tex grafts, prep, & management of central line access, hourly vital checks, calculations of weight loss & stabilizing patients during dialysis. Active participation in patient management. Administration of Epogen, Hypertonic Saline, Heparin, IV Dextrose. Operation, set up and minor maintenance of COBE dialysis units, potassium bath mixtures, shift reports, OSHA education - Hazardous Waste Management and Removal. Renal Star and Centry Net Computer Systems.

November, 1987 to June, 1992

UNIVERSITY OF VIRGINIA

Charlottesville, Virginia

Cardiovascular Technician - Full time D/E/N rotation, on call 3 to 4 nights a week and holidays. Assist in arterial and central line placement (Swan Ganz - CVP). Preparing patients for monitoring, hemodynamic profiles, blood gas labs, auto transfusion equipment, Electromedics, Hemonetics, IBM, Rapid Infusion (Hemonetics), certified IABP operator, EEG (Eagle). Performed CV Tech duties in heart, lung, liver transplants, C.A.B.G.S, thoracic and abdominal aortic SP aneurysms, aortic, bifem, spinal fusion's, assorted traumas, staff education, ordering supplies.

January, 1986 to July, 1987

GEORGETOWN UNIVERSITY HOSPITAL

Washington, D. C.

Cardiovascular Technician - Full time D/E/N rotation. EKG monitoring of a 20 bed C.S.C.U. and M.I.C.U. Responsible for arterial and Swan Ganz line maintenance, bedside Swan set ups assisting physicians. 12-lead EKG's, obtaining and interpreting shift report on individual patients for rounds, i.e., Nursing, Residents and Attendings. Use of IBM PC, Mennen and Marquette monitoring systems. Setting limits and criteria for alarms.

EDUCATION

June 1, 1998 to present

DUKE UNIVERSITY MEDICAL CENTER

Durham, North Carolina- Department of Hyperbaric and Hypobaric Medicine

Diving Accident and Hyperbaric Medicine Course-21 hours of AMA credit. *Project Dive Exploration* Field Coordinator-Divers Alert Network. Flying After Diving Research Program Participant.

9/27/2007

NASA "Building the Space Station" Study Participant. Hyperbaric Chamber Operator using Mixed Gases on Laboratory Animals. F.A.C.S. analysis collection and interpretation. Lymph Organ collection and Histo-Pathology. Doppler interpretation.

Fall 1996 to
Spring 1998

MEDICAL COLLEGE of VIRGINIA
Richmond, Virginia

Department of Microbiology/Immunology (Research level courses): Immunology, Biochemistry/ (super course), Microbiology, Bacterial Cell Physiology.

Department of Biomedical Engineering (Research Projects): *Bird-Aircraft Collision Reduction Using Microwave /Low Frequencies, Mechanism of Calcium Release and Removal from Intra-cellular Pools, Pilot Study to Assess the Efficacy of Intermittent Hyperbaric Nitrogen Treatment of Murine Acquired Immunodeficiency Virus*, supervised students on projects.

1995 to 1996

SABA UNIVERSITY SCHOOL OF MEDICINE
Saba, Netherlands-Antilles

Preclinical Sciences: Gross Anatomy, Embryology, Histology, and Medical Hyperbaric Treatment.

1992 to 1996

UNIVERSITY OF VIRGINIA SCHOOL OF MEDICINE
Charlottesville, Virginia

Medical Academic Advancement Program: Part 1; Physics, 500 Level Biochemistry, Cell Biology, Organic Chemistry.

Part 2; Medical Courses - Histology, Pharmacology, Pathology, Cell Physiology, Introduction to Clinical Medicine, Ethics, Doctor/Patient Relationship, Genetics, Biochemistry, Anatomy, Microbiology.

January, 1986 to
June, 1987

GEORGETOWN UNIVERSITY
Washington, D.C.

Graduate-Medical Course Study. Courses taken included; Mammalian Physiology, Clinical Immunology, Embryology, and Neurology.

August, 1984 to January,
1985

GEORGIA TECH. (DEKALB CAMPUS)
Atlanta, Georgia

Courses taken included: Economics, Analytic Calculus and Geometry, English prose.

August, 1981 to May, 1983

FERRUM COLLEGE
Ferrum, Virginia

Pre-med. course study. Courses taken included; 2 yr. Biology, 2 yr. Chemistry, 2 yr. Psychology, Microbiology lab prep., Vertebrate

9/27/2007

Zoology, Calculus, English Grammar and Literature, 2 yr. Western Civilization, Advanced Lifesaving, Multimedia First-Aid, C.P.R., Equestrian Team Jumping and Dressage, Waterfront Management. Extracurricular activities included: Sigma Phil Epsilon Fraternity (executive board), Chemistry Club, Outdoors Club, and Kayak instructor at Bridgewater College.

September, 1978 to June,
1981

**HARRISONBURG HIGH SCHOOL
Harrisonburg, Virginia**

College preparation course study. Extracurricular activities included; Yearbook Staff, SCA, Chorus, Theater, 2 yr. French, Varsity Wrestling, War Gamers Club, U.S. Southeastern Kayak champion, Veterinarian Assistant.

CERTIFICATIONS/LICENSES

Emergency Medical Technician, Intra-aortic Balloon Pump Operator Advanced Cardiac Life Support, Venous Puncture, and Administration of Intra-venous Medications. Mixed gas diving, Hyperbaric Chamber Operator, Research Animal Handling, F.A.C.S. Analysis. Doppler interpretation.

ORGANIZATIONS/AVOCATIONAL ACTIVITIES

Boy Scouts/Explorers, Washington Canoe Club, National Ski Patrol S.P.C.A. Divers Alert Network. American Canoe Association. United States Whitewater Team. Jockey Club, Virginia Steeplechase Association. Bethesda Center of Excellence, PADI, Technical Divers International.

Volunteer Work -Kluge Riding Rehab Program, Adolescent Counseling, Emergency Room, 4-H riding program.

Hunting, Fishing, Skiing, Rock Climbing, Bicycling, Canoeing, Steeplechasing.

1984

USA Whitewater Team Bronze Medallist, International Level Competition in Eastern and Western European Countries, World Cup.

1991 to 1993

Amateur Riders Club of America (USA Team for International horse racing Steeplechase and Flat). Licensed Owner, Trainer, and Rider for Horse Racing.

1993 to 1998

National Ski Patrol, Boy Scouts of America Leader/Coach, Questers Program Lecturer, USA Whitewater Team for 1998-99, Licensed

9/27/2007

Breeder, Trainer, Rider of Thoroughbred Race Horses, Advanced Open Water-Advanced Mixed Gas, Dry Suit and Technical Diver

1999 USA Wildwater Team (First Boat C-1); World Cup, New Zealand; Pre-World Championships, Treignac, France. Spokesman on behalf of the international athletes (France). Olympic Water Sports Expo, Baltimore, Maryland. Pan Am Silver and Bronze Medallist. Southeastern Champion and Bronze Medallist. Highest World ranked US individual Wildwater Canoeist.

2000 USA Wildwater Team; World Championship, World Cup, Championati Italiano, Mentor Junior Team (World Championship Bronze Medalist), National Silver Medalist- C1. Qualified Horse for Virginia Gold Steeplechase Races.

2001 Successful Completion of Phase I of Human Trials: "Effect of Daily Exposure to Compressed Air on Immune Response". Community of Scientist. USA Wildwater Team; Pre-World Championship, World Cup (First Boat C1), Team Leader, 2 time Gold Medalist Championati Italiano (Valstagna, Italy), Gold and 2 time Silver Medalist (Bala, Wales UK), Mentor Jr. Team Bronze Medalist.

01-101

ADMINISTRATION OF GOVERNMENT: VIRGINIA FREEDOM OF INFORMATION ACT.

HEALTH: HUMAN RESEARCH.

EDUCATIONAL INSTITUTIONS: GENERAL PROVISIONS.

Institutional Review Board is not 'public body' subject to the Act's disclosure requirements. Records generated by such board are not 'public records' prepared, owned or possessed by public body; are not required to be open for public inspection. Act's open meeting requirement does not apply to meetings of Institutional Review Boards and human research review committees.

The Honorable Thomas C. Wright Jr.

Member, House of Delegates

October 22, 2001

You ask several questions concerning the application of The Virginia Freedom of Information Act to an Institutional Review Board¹ ("IRB") of a public institution of higher learning² in the Commonwealth engaged in human research projects.

You advise that the IRBs with which you are familiar are permanent boards within public institutions of higher learning that meet on a regularly scheduled basis. Such IRBs are composed of individuals from within the institutions and from the private sector. You state that the institution pays all expenses associated with IRBs, including staff support from the institution. You also relate that public institutions of higher learning within the Commonwealth engaged in research using human subjects are required by federal and state law to submit proposed human research projects to review by an IRB.³ You explain that approval by an IRB is required prior to performing federally regulated human research projects at such universities.

The primary purpose for review by an IRB of human research projects subject to federal regulation is to "assure the protection of the rights and welfare of the human subjects."⁴ Certain criteria must be satisfied before an IRB may approve such projects. First, risks to human subjects must be minimal and reasonable in relation to anticipated benefits.⁵ In addition, selection of subjects must be equitable, and informed consent must be sought from each prospective subject and appropriately documented.⁶

Finally, the research plan must make adequate provision for monitoring and maintaining the confidentiality of data collected on human subjects and for protecting the privacy of such subjects.⁷

Sections 32.1-162.16 through 32.1-162.20 comprise Virginia's laws applicable to human research that is not subject to federal regulation for the protection of human subjects.⁸ Section 32.1-162.19(A) provides that "[e]ach institution or agency which conducts or which proposes to conduct or authorize human research *shall* establish a human research review committee." (Emphasis added.) Section 32.1-162.16 defines the term "'institution' or 'agency'" as "any facility, program, or organization owned or operated by the Commonwealth." In addition, § 32.1-162.19(A) requires anyone conducting, or proposing to conduct, human research to affiliate with an institution or agency having a human research review committee. Furthermore, § 32.1-162.19(B) stipulates that the human research review committee must review and approve any proposed human research project. Finally, § 23-9.2:3.3 provides:

Each board of visitors or other governing body of any public or private institution of higher education in which human research, as defined in § 32.1-162.16, is conducted *shall* [emphasis added] promulgate regulations pursuant to the Administrative Process Act (§ 9-6.14:1 et seq.) to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 for human research. The regulations shall require the human research committee to submit to the Governor, the General Assembly, and the president of the institution or his designee at least annually a report on the human research projects reviewed and approved by the committee and shall require the committee to report any significant deviations from approved proposals.

The use of the word "shall" in a statute generally implies that the General Assembly intends its terms to be mandatory, rather than permissive or directive.⁹ Therefore, the human research review committee performs the same functions as an IRB and, in all respects, is similar to an IRB.

You first inquire whether an IRB is a "public body" as that term is defined in The Virginia Freedom of Information Act¹⁰ (the "Act").

Section 2.2-3701 of the Act defines the term "public body" as

any authority, board, bureau, commission, district or agency of the Commonwealth ..., boards of visitors of public institutions of higher education; and other organizations, corporations or agencies in the Commonwealth supported wholly or principally by public funds. It shall include any committee [or] subcommittee ... however designated, of the public body created to perform delegated functions of the public body or to advise the public body. It shall not exclude any such committee [or] subcommittee ... because it has private sector or citizen members.

The only category under the definition of "public body" within which an IRB or a human research review committee could fall is that of "other organizations ... supported wholly or principally by public funds."¹¹ The primary goal of statutory interpretation is to ascertain and give effect to the intent of the legislature.¹² The purpose underlying a statute's enactment is particularly significant in construing it.¹³ Moreover, statutes should not be interpreted in ways that produce absurd or irrational consequences.¹⁴ Instead, they should be harmonized with other existing statutes where possible to produce a consistently logical result that gives effect to the legislative intent.¹⁵

Section 2.2-3700(B) states that the primary purpose of the Act is to

ensure[] the people of the Commonwealth ready access to records in the custody of *public officials* and free entry to meetings of *public bodies* wherein the business of the people is being conducted. [Emphasis added.] The affairs of government are not intended to be conducted in an atmosphere of secrecy since at all times the public is to be the beneficiary of any action taken at any level of government....

The provisions of [the Act] shall be liberally construed to promote an increased awareness by all persons of governmental activities and afford every opportunity to citizens to witness the operations of government.

Prior opinions of the Attorney General conclude that a variety of organizations that are not governmental agencies in the traditional sense, but which receive primary support for their activities from public funds, fall within the Act's definition of "public body."¹⁶ Both the IRB and the human research review committee are appointed by the public institution of higher learning pursuant to a statutory mandate for the purposes set forth in § 32.1-162.19 and applicable federal regulations.¹⁷ The necessary expenses incurred by the human research review committee and IRB in performing the required statutory functions are paid out of public funds from the budgets of public institutions of higher learning.

The Circuit Court of the City of Richmond construed the meaning of the term "organization" as used in the Act in a petition filed under the Act. Petitioners requested the circuit court to "order that meetings of the Animal Research Committee of the University of Virginia be treated as public meetings under the Act."¹⁸ "The Animal Research Committee ... is an arm of the University assigned to the task of establishing standards concerning the care and use of animals at the University."¹⁹ The court concluded that the term "organization," as used in the phrase "other organizations, corporations or agencies in the Commonwealth, supported wholly or principally by public funds"²⁰ means

an organization having an independent status which is charged by law with the governance of, or responsibility for, some discrete public agency. It does not include subordinate, dependent groupings of individuals who are charged with carrying out a part of the mission of a parent body.^[21]

The court reasoned that the term "organization" referred to an organization similar to those specifically enumerated in § 2.2-3701, such as legislative bodies, authorities, boards, bureaus, and commissions.²² Under the doctrine of *noscitur a sociis*,²³ the court was required to construe the term "organization" "with reference to the words it is used with" in the Act.²⁴

Under the facts you provide, IRBs and human research review committees are supported wholly by public funds, but do not perform delegated functions of institutions of higher learning. I cannot conclude that an IRB or a human research review committee is an independent entity charged by law with the governance of, or responsibility for, some discrete public agency. It is clear that such boards and committees are subordinate, dependent groupings of individuals charged with effecting a mission of public institutions of higher learning. Therefore, I must conclude that an IRB is not a "public body" as that term is defined in the Act.

You next ask whether the records generated by an IRB are "public records" as that term is defined by the Act.

Section 2.2-3701 broadly defines the term "public records" to mean

all writings and recordings that consist of letters, words or numbers, or their equivalent, set down by handwriting, typewriting, printing, photostatting, photography, magnetic impulse, optical or magneto-optical form, mechanical or electronic recording or other form of data compilation, however stored, and regardless of physical form or characteristics, prepared or owned by, or in the possession of a public body or its officers, employees or agents in the transaction of public business.

"Where a statute is unambiguous, the plain meaning is to be accepted without resort to the rules of statutory interpretation."²⁵ All public records are open for inspection and copying during regular office hours, unless otherwise specifically provided by law.²⁶ The definition of "public records" in the Act includes "all writings ... that consist of letters, words or numbers, or their equivalent, set down ... regardless of physical form or characteristics, prepared or owned by, or in the possession of a public body."²⁷ The IRB and the human research review committees are not public bodies,²⁸ subject to the Act's disclosure requirements. The Act requires that "[a]ny exemption from public access to records ... shall be narrowly construed."²⁹ Since I conclude that an IRB is not a "public body" as defined in the Act, I must also conclude that records generated by an IRB are not "public records" prepared or owned by, or in the possession of, a public body.

You next ask whether the open meeting requirements set forth in § 2.2-3707 of the Act apply to the meetings of IRBs.

"The provisions of [the Act] shall be liberally construed to promote an increased awareness by all persons of governmental activities and afford every opportunity to citizens to witness the operations of government."³⁰ Since I am of the opinion that IRBs and human research review committees do not fall within the Act's definition of "public body," I must also conclude that they would not be subject to the Act's open meeting requirement. Accordingly, I am of the opinion that the Act does not require that the meetings of these boards and committees be open to the public.

Your final inquiry is whether IRB records are "public records" open to inspection under § 2.2-3704 of the Act.

Section 2.2-3704(A) provides that, "[e]xcept as otherwise specifically provided by law, all public records shall be open to inspection and copying by any citizens of this Commonwealth during the regular office hours of the custodian of such records." Section 2.2-3705 contains 77 exceptions to the mandatory disclosure provisions of § 2.2-3704. Section 2.2-3705(A)(20) clearly excludes

[d]ata, records or information of a proprietary nature produced or collected by or for faculty or staff of public institutions of higher education ... in the conduct of or as a result of study or research on medical, scientific, technical or scholarly issues, whether sponsored by the institution alone or in conjunction with a governmental body or a private concern, where such data, records or information has not been publicly released, published, copyrighted or patented.

IRBs and human research review committees are not, in my opinion, public bodies. As a result, these boards and committees are not subject to the provisions of the Act. The records of an IRB, therefore, are not subject to inspection and copying by any citizen. Consequently, I must conclude that the Act does not require that the records of an IRB be open for public inspection.

¹An Institutional Review Board is "any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research [regulated by the Food and Drug Administration] involving human subjects." 21 C.F.R. § 56.102(g) (2001).

²Public institutions of higher learning in the Commonwealth include "The College of William and Mary in Virginia, at Williamsburg; the rector and visitors of Christopher Newport University, at Newport News; Longwood College, at Farmville; the Mary Washington College, at Fredericksburg; George Mason University, at Fairfax; the James Madison University, at Harrisonburg; Old Dominion University, at Norfolk; the State Board for Community Colleges, at Richmond; the Virginia Commonwealth University, at Richmond; the Radford University, at Radford; the Roanoke Higher Education Authority and Center; the rector and visitors of the University of Virginia, at Charlottesville; the University of Virginia's College at Wise; the Virginia Military Institute, at Lexington; the Virginia Polytechnic Institute and State University, at Blacksburg; the Virginia Schools for the Deaf and the Blind; the Virginia State University, at Petersburg; Norfolk State University, at Norfolk; the Woodrow Wilson Rehabilitation Center, at Fishersville; the Medical College of Hampton Roads; and the Southwest Virginia Higher Education Center." Va. Code Ann. § 23-14 (Michie Supp. 2001).

³See 45 C.F.R. pt. 46 (2000) (regulations of Department of Health and Human Services applicable to "Protection of Human Subjects"); 21 C.F.R. pt. 56 (2001) (regulations of Food and Drug Administration applicable to "Institutional Review Boards"); Va. Code Ann. tit. 32.1, ch. 5.1, §§ 32.1-162.16 to 32.1-162.20 (Michie Repl. Vol. 2001) (statutes governing human research conducted by institution or agency of Commonwealth).

⁴See 21 C.F.R. § 56.102(g).

⁵See 45 C.F.R. § 46.111(a)(1)-(2).

⁶See *id.* § 46.111(a)(3)-(5).

⁷See *id.* § 46.111(a)(6)-(7).

⁸See § 32.1-162.20.

⁹See *Andrews v. Shepherd*, 201 Va. 412, 414-15, 111 S.E.2d 279, 281-82 (1959); *see also Schmidt v. City of Richmond*, 206 Va. 211, 218, 142 S.E.2d 573, 578 (1965); *Op. Va. Att'y Gen.*: 1998 at 56, 58; 1996 at 178, 178; 1991 at 238, 240; 1989 at 250, 251-52; 1985-1986 at 133, 134.

¹⁰Va. Code Ann. §§ 2.2-3700 to 2.2-3714 (Matthew Bender Repl. Vol. 2001).

¹¹Section 2.2-3701.

¹²See *Turner v. Commonwealth*, 226 Va. 456, 459, 309 S.E.2d 337, 338 (1983).

¹³*VEPCO v. Prince William Co.*, 226 Va. 382, 388, 309 S.E.2d 308, 311 (1983).

¹⁴*McFadden v. McNorton*, 193 Va. 455, 461, 69 S.E.2d 445, 449 (1952); *see Op. Va. Att'y Gen.*: 1993 at 192, 196; 1991 at 5, 7; 1986-1987 at 307, 308.

¹⁵2A Norman J. Singer, *Sutherland Statutory Construction* § 46.05 (5th ed. 1992 & Supp. 1999); 1993 *Op. Va. Att'y Gen.*, *supra*.

¹⁶See, e.g., *Op. Va. Att'y Gen.*: 1984-1985 at 431 (Student Senate of Old Dominion University); 1983-1984 at 447, 448 (Governor's Advisory Board of Economists and Governor's Advisory Board on Revenue Estimates); 1982-1983 at 719 (Fairfax Hospital Association); *id.* at 726 (volunteer fire department); 1977-1978 at 482 (university honor committee); 1975-1976 at 406, 407; 1974-1975 at 584, 584 (General Professional Advisory Committee, composed of university presidents, established by State Council of Higher Education to serve Council in advisory capacity). *But see Op. Va. Att'y Gen.*: 1978-1979 at 316 (city mayor's citizen advisory committee is not subject to Act; is not created by public body, performs no delegated functions of public body, does not advise public body, and receives no public funding); 1974-1975, *supra*, at 584-85 (voluntary association of college presidents, with no official status as creature of State Council of Higher Education and receiving no public funds, is excluded from Act).

¹⁷See 45 C.F.R. § 46.111(a); 21 C.F.R. § 56.102(g).

¹⁸*Students for Animals v. University of Virginia*, 12 Va. Cir. 247, 247 (1988).

¹⁹*Id.*

²⁰Section 2.2-3701 (defining "public body").

²¹*Students for Animals*, 12 Va. Cir. at 249.

²²*Id.*

²³"The meaning of a word ... takes color and expression from the purport of the entire phrase of which it is a part, and it must be construed so as to harmonize with the context as a whole." *Kohlberg v. Va. Real Estate Comm.*, 212 Va. 237, 239, 183 S.E.2d 170, 172 (1971). "[I]t is known by its associates." *Black's Law Dictionary* 1084 (7th ed. 1999) (noting Latin derivation of *noscitur a sociis*).

²⁴*Students for Animals*, 12 Va. Cir. at 249.

²⁵*Last v. Virginia State Bd. of Medicine*, 14 Va. App. 906, 910, 421 S.E.2d 201, 205 (1992).

²⁶Section 2.2-3704(A).

²⁷*Id.*

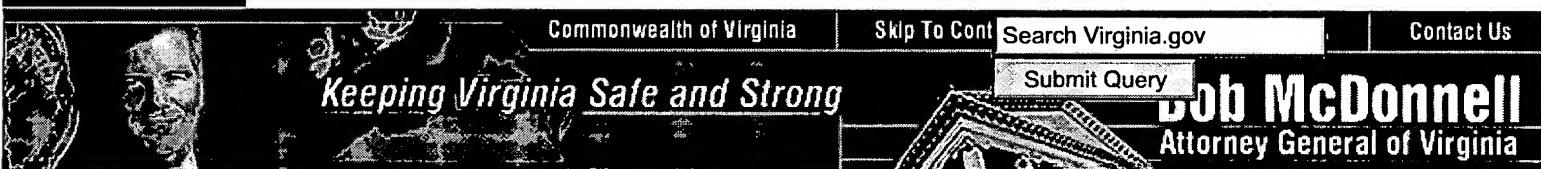
²⁸Section 2.2-3701 (defining "public body").

²⁹Section 2.2-3700(B).

³⁰*Id.*

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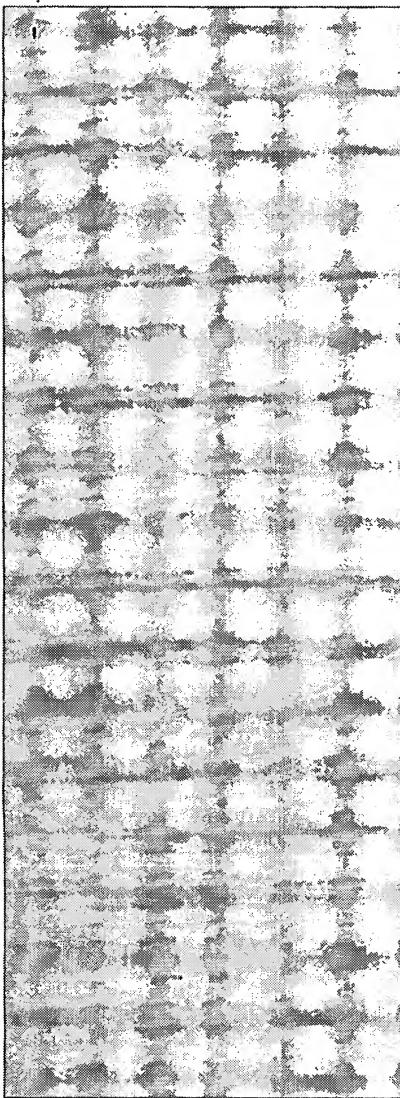
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Opinion #	Requestor	Summary
01-101	The Honorable Thomas C. Wright Jr. Member, House of Delegates	Institutional Review Board is not 'public body' subject to the Act's disclosure requirements. Records generated by such board are not 'public records' prepared, owned or possessed by public body; are not required to be open for public inspection. Act's open meeting requirement does not apply to meetings of Institutional Review Boards and human research review committees.
01-093	The Honorable Judy L. Worthington Clerk, Circuit Court of Chesterfield County	Circuit court, and not clerk, must make specific finding that indigent defendant has demonstrated particularized need for free copy of his trial transcript. Funds expended for preparation of transcript for indigent defendant may be reimbursed pursuant to circuit court order specifically providing for such payment. Indigent defendant previously provided with copy of arrest warrant, indictments and conviction orders is not entitled to additional copies. Circuit court clerk may not waive fees for copying document previously furnished to indigent defendant at no charge.
01-088	The Honorable Glenn M. Weatherholtz Member, House of Delegates	Locality, which contributes to its retirees' health insurance, may take into account state credit paid toward health insurance of retiree of local constitutional officer.
01-091	The Honorable William Page Johnson II Commissioner of the Revenue for the City of Fairfax	Commissioner of revenue may publish on Internet web page names of businesses licensed to do business in commissioner's locality.

Virginia's Attorney General at Work:
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01-035 The Honorable Ross A. Mugler
Commissioner of the Revenue for the City
of Hampton

00-108 The Honorable Susan P. Ford
Commissioner of the Revenue for
Powhatan County

**Exception to federal
preemption applies to local
license tax levied on
businesses participating in
TRICARE health insurance
program because tax is
imposed on broad range of
business activity and not
solely on cost of individual
health care benefits.**

**Commissioner of revenue has
no authority to effect change
in real property ownership on
land books based on recorded
deed of gift, with attached
holographic will that has not
been recorded or probated.**